APR 6 2006

K 051927

6.0 510(k) SUMMARY OF THE TECHLAB® *ASCA-CHEK* TEST

Contact Information

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Date Prepared March 31, 2006

Product and Trade Name TECHLAB® *ASCA-CHEK*

Classification Class II, 21 CFR 866.5785

Predicate Devices

- QUANTA Lite™ ASCA IgG (K000732). This is an ELISA for the semi-quantitative detection of anti-*Saccharomyces cerevisiae* IgG antibodies (ASCA) in human serum as an aid for the differential diagnosis of Crohn's disease from ulcerative colitis.
- QUANTA Lite™ ASCA IgA (K000733). This is an ELISA for the semi-quantitative detection of anti-*Saccharomyces cerevisiae* IgA antibodies (ASCA) in human serum as an aid for the differential diagnosis of Crohn's disease from ulcerative colitis.
- ImmuLisa Anti-*Saccharomyces cerevisiae* Antibody (ASCA) IgG (K032850). An enzyme linked immunoassay (ELISA) for the detection and semi-quantitation of anti-*Saccharomyces cerevisiae* (IgG) in human serum of patients with inflammatory bowel disorder (IBD) as an aid in the diagnosis of Crohn's disease (CD).
- ImmuLisa Anti-*Saccharomyces cerevisiae* Antibody (ASCA) IgA (K032860). An enzyme linked immunoassay (ELISA) for the detection and semi-quantitation of anti-*Saccharomyces cerevisiae* (IgA) in human serum of patients with inflammatory bowel disorder (IBD) as an aid in the diagnosis of Crohn's disease (CD).

Intended Use

The TECHLAB® *ASCA-CHEK* test is an ELISA for the qualitative detection of human anti-*S. cerevisiae* antibodies (ASCA) in feces. **The test result is used as an aid in the diagnosis of Crohn's disease in combination with clinical and other laboratory findings.** FOR *IN VITRO* DIAGNOSTIC USE.

Device Description

The TECHLAB® *ASCA-CHEK* test is an enzyme-linked immunoassay (ELISA) for the measurement of human anti-*S. cerevisiae* antibodies in feces as an aid in the diagnosis of Crohn's disease. The assay utilizes antigens of *S. cerevisiae* for capture and a polyvalent anti-human immunoglobulin conjugate. When human ASCA is present in the fecal specimen, the specific immunoglobulins bind to the *S. cerevisiae* antigens that are immobilized in the test well. Following this binding step, the polyvalent anti-human

horseradish peroxidase (HRP) conjugate binds to the ASCA and reacts with the substrate to produce a positive result. The measurement of fecal ASCA is an aid in the diagnosis of Crohn's disease within the setting of differentiating Crohn's disease from ulcerative colitis. This noninvasive diagnostic method is simple to perform and requires only a fecal specimen for the analysis.

Comparative information of equivalent devices

Test	Description	Format	Turn-around time	Limitations
TECHLAB® *ASCA-CHEK*	Intended for determining the presence of **fecal** antibodies against *S. cerevisiae* (ASCA antibodies) in **adult and pediatric IBD and IBS patients** as an aid in the diagnosis of Crohn's disease.	ELISA	75 minutes	ASCA are found in about 50 to 60% of persons with Crohn's disease. The two-step ELISA procedure requires multiple wash steps. The test does not identify all persons with Crohn's disease.
QUANTA Lite™ ASCA (*S. cerevisiae*) IgG ELISA (K000732)	Intended for determining the presence of **serum** antibodies against *S. cerevisiae* (ASCA antibodies) **in adult IBD patients**	ELISA	90 minutes	ASCA serum antibodies are found in about 50 to 60% of persons with Crohn's disease. The test does not identify all persons with Crohn's disease.
QUANTA Lite™ ASCA (*S. cerevisiae*) IgA ELISA (K000733)	Intended for determining the presence of **serum** antibodies against *S. cerevisiae* (ASCA antibodies) **in adult IBD patients**	ELISA	90 minutes	ASCA serum antibodies are found in about 50 to 60% of persons with Crohn's disease. The test does not identify all persons with Crohn's disease.
ImmuLisa Anti-Saccharomyces Antibody (ASCA) IgG (K032850)	Intended for determining the presence of **serum** antibodies against *S. cerevisiae* (ASCA antibodies) in IBD patients	ELISA	90 minutes	ASCA serum antibodies are found in about 50 to 60% of persons with Crohn's disease. The test does not identify all persons with Crohn's disease.
ImmuLisa Anti-Saccharomyces Antibody (ASCA) IgA (K032860)	Intended for determining the presence of **serum** antibodies against *S. cerevisiae* (ASCA antibodies) in IBD patients	ELISA	90 minutes	ASCA serum antibodies are found in about 50 to 60% of persons with Crohn's disease. The test does not identify all persons with Crohn's disease.

Summary of Performance Data

When comparing the *ASCA-CHEK* test results for all 4 Study Sites to clinical assessments for disease diagnosis **including** the healthy controls (N=353), the sensitivity for distinguishing Crohn's disease from ulcerative colitis, irritable bowel syndrome and healthy persons was 57% and the specificity was 91%.

Statistical analysis of the *ASCA-CHEK* test results compared to clinical diagnosis for Crohn's disease, ulcerative colitis and irritable bowel syndrome, and from healthy persons.

N=353	Crohn's disease	Non-Crohn's disease	Total
***ASCA-CHEK* test Positive**	81	20	101
***ASCA-CHEK* test Negative**	61	191	252
Total	142	211	353

		95% Confidence Intervals
Sensitivity	57.0%	48.5 – 65.2%
Specificity	90.5%	85.5 – 94.0%
Predicted Positive Value	80.2%	70.8 – 87.2%
Predicted Negative Value	75.7%	69.9 – 80.9%
Correlation	77.1%	72.5 – 81.0%

When comparing the *ASCA-CHEK* test results for all 4 sites to clinical assessments for disease diagnosis **excluding** healthy controls (N=285), the sensitivity for distinguishing Crohn's disease from ulcerative colitis and irritable bowel syndrome was 57% and the specificity was 87%.

Statistical analysis of the *ASCA-CHEK* test results compared to the clinical diagnosis for Crohn's disease, ulcerative colitis and irritable bowel syndrome.

N=285	Crohn's disease	Ulcerative colitis and irritable bowel syndrome
***ASCA-CHEK* test Positive**	81	19
***ASCA-CHEK* test Negative**	61	124

		95% Confidence Intervals
Sensitivity	57.0%	48.5 – 65.2%
Specificity	86.7%	79.8 –91.6 %
Predicted Positive Value	81.0%	71.7 – 87.9%
Predicted Negative Value	67.0%	59.7 – 73.7%
Correlation	71.9%	65.8 – 77.0%

Summary of Performance Data (cont'd)

When comparing the *ASCA-CHEK* test results for both **pediatric** sites to clinical assessments for disease diagnosis **excluding** healthy controls (N=146), the sensitivity for distinguishing Crohn's disease from ulcerative colitis and irritable bowel syndrome was 48% and the specificity was 92%.

Statistical analysis of the *ASCA-CHEK* test results compared to the clinical diagnosis for Crohn's disease, ulcerative colitis and irritable bowel syndrome.

N=146	Crohn's disease	Ulcerative colitis and irritable bowel syndrome
***ASCA-CHEK* test Positive**	31	7
***ASCA-CHEK* test Negative**	33	75

		95% Confidence Intervals
Sensitivity	48.4%	35.9 – 61.2%
Specificity	91.5%	82.7 – 96.2%
Predicted Positive Value	81.6%	65.1 – 91.7%
Predicted Negative Value	69.4%	59.7 – 77.8%
Correlation	72.5%	63.9 – 79.4%

The *ASCA-CHEK* test was tested at four clinical sites and included a mixed patient population including both pediatric and adult patients. The table below shows the comparison of clinical sensitivity and specificity for fecal ASCA in pediatric and adult patient populations. There was no difference observed in clinical performance of the *ASCA-CHEK* test between pediatric and adult patients. The table below shows a summary of the *ASCA-CHEK* test results between the four clinical sites.

Four clinical site study*:

	Site 1	Site 2	Site 3	Site 4
	Pediatric: n=78	Adult: n=107	Pediatric: n=23	Ped. and Adult: n=82
Sensitivity	**40.0%**	**63.3%**	**54.5%**	**63.8%**
Specificity	**88.5%**	**81.1%**	**91.7%**	**91.4%**

***Total n=290 (Excludes the 53 healthy adults)**

Summary of results for the *ASCA-CHEK* test and the QUANTA™ Lite tests using paired fecal and serum specimens

The *ASCA-CHEK* and QUANTA™ Lite tests showed similar results in all categories with the *ASCA-CHEK* test showing a total of 64% positive results for subjects with CD compared to 77% positive for the QUANTA™ Lite test. The results for the different categories are shown in the table below.

Clinical Assessments N = 82	**Total # of patients**	***ASCA-CHEK* Fecal Positive result**	**QUANTA™ Lite Serum Positive results**
Total IBD	70	31 (44%)	37 (53%)
Total **Crohn's Disease**	47	30 (64%)	36 (77%)
Total **Ulcerative Colitis**	23	1 (4%)	1 (4%)
Total Other: **IBS, Cancer, indeterminant**	7	1 (14%)	1 (14%)
Total **Healthy Persons**	5	1 (20%)	2 (40%)

When comparing the *ASCA-CHEK* test results done in feces compared to the QUANTA Lite™ ASCA IgG test performed in serum for paired specimens (fecal/serum) collected from both pediatric and adult sites (N=82), the positive percent agreement was 70% and the negative percent agreement was 88%.

Statistical analysis of the *ASCA-CHEK* test results compared to the clinical diagnosis for Crohn's disease, ulcerative colitis and irritable bowel syndrome.

N=82	**QUANTA Lite™ ASCA IgG Serum test Positive**	**QUANTA Lite™ ASCA IgG Serum test Negative**	**Total**
***ASCA-CHEK* test Positive**	28	5	33
***ASCA-CHEK* test Negative**	12	37	49
Total	40	42	82

		95% Confidence Intervals
Percent Positive Agreement	70.0%	53.3 – 82.9%
Percent Negative Agreement	88.1%	73.6 – 95.5%
Overall Percent Agreement	79.3%	69.6 – 86.1%

Based on these findings, we believe the *ASCA-CHEK* test is substantially equivalent to other diagnostic tests now used to evaluate patients suspected of having inflammatory bowel disease. Further, our results demonstrate that the *ASCA-CHEK* test is suitable as an *in vitro* diagnostic aid to help identify patients with Crohn's disease when assessing patients with chronic intestinal illnesses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 6 2006

TECHLAB, Inc.
c/o David M. Lyerly, Ph.D.
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Re: k051927
Trade/Device Name: TECHLAB® ASCA-CHEK
Regulation Number: 21 CFR 866.5785
Regulation Name: Anti-Saccharomyces cerevisiae (ASCA) Test System
Regulatory Class: Class II
Product Code: NBT
Dated: July 15, 2005
Received: July 18, 2005

Dear Dr. Lyerly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K 051927

Device Name: TECHLAB® *ASCA-CHEK*

Indications For Use:

The TECHLAB® *ASCA-CHEK* test is an ELISA for the qualitative detection of human anti-*S. cerevisiae* antibodies (ASCA) in feces. The test result is used as an aid in the diagnosis of Crohn's disease in combination with clinical and other laboratory findings.
FOR *IN VITRO* DIAGNOSTIC USE.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K051927